

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

ASHLEY STOCK,)	
)	
<i>Plaintiff</i>)	
)	
v.)	Case No. 2:2022-cv-04104-DGK
)	
JAMES L. GRAY, III, <i>et al.</i> , in their)	Hon. David Gregory Kays
official capacities as officers or)	
members of the Missouri Board of)	
Pharmacy,)	
)	
<i>Defendants</i>)	

REPLY SUGGESTIONS IN SUPPORT OF DEFENDANTS'
MOTION FOR SUMMARY JUDGMENT

ARGUMENT

I. Plaintiff lacks standing due to key admissions that reveal she cannot credibly claim to face professional liability under Section 338.055.7's competency requirements.

First, based on key admissions, Plaintiff lacks standing to press this suit because her speech is not “arguably proscribed” and there exists no “credible threat of enforcement.” *Parents Defending Education v. Linn Mar Cmty. Sch. Dist.*, 83 F.4th 658 (8th Cir. 2023) (following *S.B.A. List v. Driehaus*, 573 U.S. 149 (2014)). There is no credible threat of professional liability for competent professional communication. Def. SUMF ¶ 52, Ex. G. Plaintiff admits that she relies upon the Board’s guidance, resources at FDA.gov, among other sources, in making a professional decision. Def. SUMF ¶ 47. Plaintiff has not proven that her opinions are outside recognized professional knowledge, nor is it likely that she would do so because professional competence is an ethical requirement that must exist in reference to professional knowledge. Def. SUMF ¶ 35, 36, 59. Plaintiff’s practice is to pursue more information when encountering an off-label or even on-label prescription with quantities and dosing that are excessive or even under-utilizing dosage. Def. SUMF ¶ 42. Plaintiff believes in giving patients the best information available. Def. SUMF ¶ 45. As a result, Plaintiff’s alleged controversy here is hypothetical, not real and immediate. See Def. Am. SIS, p. 38-43. Plaintiff concedes that she has never had an argument, and her declaration does not support any “arguably proscribed” conduct or speech under 338.055.7 that is subject to a “credible threat of enforcement.” Plaintiff’s description of a recent interaction with a different prescription not at issue where she

“contacted the physician to let him know the problem and suggested an alternative treatment” regarding medications not mentioned under 338.055.7 does not amount to “arguably proscribed” conduct. Plaintiff does not allege that the contact was made “to dispute,” so it does not confer standing. Ex. A, ¶ 7. Plaintiff testified that there is no scenario where she does not begin a conversation by seeking information. Def. SUMF 10-11. Plaintiff’s supplemental statement that “[d]isagreements between pharmacist and prescribing physician [...] arise naturally” may be true, but disagreements that arise naturally do not constitute the conduct prohibited by the statute. The statute prohibits a pharmacist from initiating contact with a prescribing physician or patient “to dispute the efficacy of ivermectin tablets or hydroxychloroquine sulfate tablets for human use,” which is distinct from information-seeking, consultation, or as Plaintiff testified, a request “to provide evidence based medicine to prove that the medication was being used at a safe and effective dose for the diagnosis [.]” Def. SUMF 10.

Whether complaints are filed pursuant to 338.055.7 or another provision is outside the Defendants’ and this Court’s control, so Plaintiff continues to lack redressability. The same holds true for professional liability because Plaintiff faces no discernable case of professional discipline with a particular patient context, actual pharmacist conduct or speech, or professional liability imposed to examine. Def. SUMF ¶ 49.

Further, Plaintiff argues that “338.055.7 is categorical not contextual.” Doc. 65, Pl. SIO, p. 20, fn. 3. At the same time, she admits that she does not dispute the

drugs' efficacy categorically: "There would be no reason for me to make such a categorical statement[.]" Def. SUMF ¶ 46. Defendants' expert addressed such categorical denunciations, testifying that "Stating FDA-approved medications for human use are not effective for human use would be false, misleading, and likely violate multiple standards." Def. SUMF ¶ 64. Together, these admissions also mean that Plaintiff has no credible expectation of professional liability, and so Plaintiff lacks standing.

Plaintiff's difference over the interpretation of what constitutes pharmacist "contact" is at odds with her testimony that she considers "a patient's approach at the counter in a typical interaction to be the patient contacting her and inviting her into a pharmacist-patient relationship and implicit permission to contact the doctor from the patient." Def. SUMF ¶ 8. When contact is initiated by a patient or doctor, a pharmacist has not initiated the contact and the statute does not clearly apply. This admission further deprives Plaintiff of standing. Plaintiff's argument that the reading would be "untenable" because "there could never be a retail pharmacist-initiated contact" is not true because the remainder portion could be conditionally effective as a particular prohibition against uninitiated contact. That reading would only strengthen the status of Section 338.055.7 as a restriction on conduct that "incidentally burdens speech," if at all.¹

¹ As Plaintiff argues in her SIO, p. 16, "no law should be construed to render a 'clause, sentence, or word' 'superfluous, void, or insignificant.'" *RW Inc. v. Andrews*, 534 U.S. 19, 31 (2001); *accord Mountain States Tel. & Tel. Co. v. Pueblo of Santa Ana*, 472 U.S. 237, 249 (1985) (applying the "elementary canon of construction that a statute should be interpreted so as not to render one part inoperative") (citations omitted); Antonin Scalia & Bryan A. Garner, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 174 (2012) ("every word and every provision is to be given effect").

Plaintiff argues that “credible threat of enforcement” prong is satisfied and cites *St. Paul Area Chamber of Commerce*, but the dispensing of pharmaceutical information, specifically relating to the approval status for human use as approved by the FDA, the current standard of care, or evidence-based scientific data/research, is not the same type of conduct as election-related campaign contributions discussed in *St. Paul Area Chamber of Commerce*. 439 F.3d 481, 486 (8th Cir. 2006). Sharing competent pharmaceutical information in a commercial capacity is not “expressive activity” in this context, and the Guidance Statement provides compelling evidence that no credible threat of professional liability exists for the Plaintiff. Though the Plaintiff argues that Defendant is not bound to it, the Guidance Statement presents a consistent interpretation of the statutory requirements of 338.055, applying professional competency requirements to all medications, and Plaintiff has not proven that the Guidance Statement is applied inconsistently, is likely to change, or imposes any particular viewpoint requirement. Rather, “Section 338.055.7 does not prohibit sharing truthful and accurate medical/drug information with prescribers or patients, consistent with the standard of care, current FDA guidance, or evidence-based scientific data/research.” Def. SUMF ¶ 52, Ex. G.

II. Section 338.055.7 survives scrutiny under *NetChoice* balancing or any other appropriate standard and is not viewpoint discrimination because it allows for multiple views.

The Plaintiff observes that to be successful on a facial suit based on the First Amendment, a plaintiff must show that “a substantial number of [the law's] applications are unconstitutional, judged in relation to the statute's plainly

legitimate sweep.” *Moody v. NetChoice, LLC*, 144 S. Ct. 2383, 2388 (2024)(citing *Americans for Prosperity Foundation v. Bonta*, 594 U.S. 595, 615). In analyzing every possible application of this law, the constitutional applications far outweigh any unconstitutional applications.

First, if the Court were to grant Plaintiff’s interpretation that the statute “is categorical not contextual,” Doc. 65, Pl. SIO, p. 20, fn. 3, the statute may be read to prohibit “categorical” disputes regarding “human use.” This supports the Defendants’ position because categorical denials as to the human use of the human forms of the two medications are exactly the type of “fraudulent,” “deceptive,” “dishonest,” and “incompetent” statements that were a basis for public concern as a result of the confusing media that emphasized animal forms of the medications in a way that disrupted the practice of medicine and caused widespread confusion. Pl. Am. SIS, p. 35-37, 47-49 (See *Apter v. Dep’t of Health & Human Services*, 80 F.4th 579, 583 (5th Cir. 2023)). If the Court adopts the Defendants’ reading of the statute—situated in the statutory context of 338.055 as explained by the Guidance Statement— the number of valid applications becomes context dependent based on professional standards that require competence rather than any particular view: “Section 338.055.7 does not prohibit a pharmacist from sharing truthful and accurate medical/drug information with prescribers or patients, consistent with the standard of care, current FDA guidance, or evidence-based scientific data/research.” Def. SUMF ¶ 52, Ex. G. As a result, Plaintiff cannot show that “a substantial number of [Section 338.055.7]’s applications are unconstitutional, judged in relation to the statute’s plainly

legitimate sweep.” Unlike in *NetChoice*, which concerned social-media platform content moderation, Section 338.055.7 has a plainly legitimate sweep as a professional competence requirement in the practice of pharmacy, a commercial context, passed to address a public health concern.

A lesser standard may be employed under which Defendants may prevail. In his concurrence in *NetChoice*, Justice Thomas discussed *Zauderer*’s applicability, where “the Court held that laws requiring the disclosure of factual information in commercial advertising may satisfy the First Amendment if the disclosures are reasonably related to the Government’s interest in preventing consumer deception.” *Moody v. NetChoice, LLC*, 144 S. Ct. 2383, 2413 (2024)(citing 105 S.Ct. 2265 (internal citations omitted). Unlike *303 Creative LLC*, 143 S.Ct. 2298, which pertained to expressive content of website design, Section 338.055.7’s disclosure requirement is related to pharmacist conduct, and if the pharmacist “contact” and “to dispute” conditions are met, speech, regarding the human forms of the medications for human use. But the content of the speech is not tied to a particular viewpoint, but to competency. Def. SUMF ¶ 52, Ex. G. There is a compelling interest in preventing consumer deception here and requiring competence from pharmacists. If evaluated under *Zauderer*, the disclosure requirements regarding the efficaciousness for human use of the medications are reasonably related to the State’s interest in preventing deception of consumers. Any required disclosures do not unduly burden the Plaintiff because professional competence satisfies 338.055.7. The statute is narrowly tailored to serve compelling government interests, see Def. Am. SIS, pp. 45-49, and addresses

conduct or speech “inherently likely to deceive.” *In re R.M.J.*, 455 U.S., at 202.

Plaintiff’s argument that “viewpoint discrimination” is at work in Section 338.055.7, RSMo, rings hollow in view of the statutory context of Section 338.055, which details professional standards for pharmacist competence and behavior. *See, e.g.*, § 338.055.2(5)². The statutory context the Board Guidance recognizes provides for multiple viewpoints based on “evidence-based scientific data/research,” a consistent approach applied across all medications—not a “new” approach for litigation purposes. Def. SUMF ¶ 52, Ex. G. From the outset, Plaintiff has stated that she would not accept any assurances and “would still reasonably fear the effects of complaints,” Doc. 1 at ¶ 85, but even so, the Guidance Statement’s explanation of the statutory framework informs pharmacists that 338.055.7 requirements are read harmoniously with the entire statutory framework and allow for evidence-based practice.

III. Conduct or speech that is “incompetent,” “fraudulent,” “likely to deceive,” or which presents “some grave and imminent threat the Government has the power to prevent” as Section 338.055.7 statutory context proscribes, is not protected by the First Amendment.

Because the statute allows for multiple professional views and for reasons discussed above, the statute is not viewpoint discrimination. The First Amendment does not cover Plaintiff’s proposed speech because the conduct prohibited by the statute, to the extent it covers speech, is among the type of communications that

² “[I]ncompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter” are causes for discipline, for example.

government may prohibit as “likely to deceive.” *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 563–64 (1980); see Def. SIO, pp. 29-32. *Zauderer* discussed above at pp. 6-7, is not limited by *303 Creative LLC*, 143 S.Ct. 2298, and nothing prevents regulation of commercial context “inherently likely to deceive.” *In re R.M.J.*, 455 U.S., at 202.

Plaintiff argues that Section 338.055.7 does not merely capture unprotected fraud, but does not provide an example of prohibited speech that is otherwise competent. Plaintiff’s citation to *Alvarez* where the Court wrote that is “perilous to permit the state to be the arbiter of truth” includes the categories of “philosophy, religion, history, the social sciences, the arts [...]”. But these areas are different than pharmacy. The First Amendment’s coverage does not extend to cover speech that is demonstrably “fraud” or which would create “some grave and imminent threat the government has power to prevent,” among other types of unprotected speech. *United States v. Alvarez*, 567 U.S. 709, 717–18 (2012). “The government’s authority to “protect people against fraud [...] has always been recognized in this country and is firmly established.” *Donaldson v. Read Mag.*, 333 U.S. 178, 190 (1948). Defendant’s expert believed that the FDA’s “you are not a horse” tweet contributed to public concern, Def. SUMF ¶ 103, and substantial reported confusion between the animal and human forms of the medications at issue here justifies the government’s competency requirement. Pl. Am. SIS, p. 35-37, 47-49 (*See Apter v. Dep’t of Health & Human Services*, 80 F.4th 579, 583 (5th Cir. 2023). To address the alleged “grand inconsistency [...] in Defendants’ theory of law” that Plaintiff alleges in her

introduction, Pl. SIO, p. 2, between the “FDA’s sophomoric tweets” and the interpretation of the law to provide a safe harbor for information sharing “consistent with... current FDA guidance,” one needs only recall that the statute’s coverage is over pharmacist conduct in their professional capacity. Pharmacists are expected to understand and communicate information about medications with professional competence, Def. SUMF ¶ 35, and they have a “duty to maintain knowledge and abilities as new medications, devices and technologies become available and as health information advances.” Def. SUMF ¶ 36. Society relies on this communication of factual information and has a reasonable expectation to expect competency from pharmacists, whether it is distinguishing between the animal and human forms of medications or incorporating evidence-based scientific data/research in their practice.

IV. To the extent that any First Amendment concerns are implicated that are not sufficiently justified, a narrowing construction is available.

Plaintiff admits that a narrowing construction is available if the statutory language is “fairly susceptible” to a “reasonable and readily apparent” construction. Pl. SIO, p. 17, citing *United States v. Stevens*, 559 U.S. 460, 481 (2010)(further citation omitted). Section 338.055.7’s language, read in the statutory context of Section 338.055, is fairly susceptible to the reasonable and readily apparent construction provided by the Guidance Statement that accounts for the professional conduct requirements of Section 338.055.2(5), accounts for various perspectives and sources that inform a pharmacist’s professional knowledge, and consistently applies the standards across all medications.

Conclusion

For these reasons, the Court should deny Plaintiff's motion for summary judgment, and grant summary judgment for Defendants.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 2, 2024, the foregoing was filed using the Court's electronic filing system, which will send notification to parties of record.

/s/ Matthew J. Tkachuk